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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,761

11/13/2003

Barry E. Boyes

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EXAMINER

MOSS, KERI A

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

05/15/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No. 10/713,761	Applicant(s) BOYES ET AL.	
	Examiner KERI A. MOSS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008 and 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1,6-26 and 28-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-36 are pending.

Election/Restrictions

2. Claims **1, 6-26 and 28-36** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 13, 2008.

Response to Amendment

3. Rejections under 35 USC 112, 2nd paragraph have been withdrawn in light of applicants' arguments and amendments

Rejections under Bailey and Jindal have been maintained, but modified.

Rejection under Mizushina has been withdrawn in light of applicant's arguments.

Claim Interpretation

4. The phrase "at least uncertain" is interpreted to mean that the specificity of the first stationary phase for one constituent present in the sample may be uncertain or certain. The phrase "at least uncertain" is indefinite, but appears to denote a scale of specificity wherein one end of the scale is uncertain. The Examiner has interpreted that this scale of specificity ranges from uncertain to certain.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims **2-5 and 27** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "at least uncertain" is vague and indefinite. It is unclear what the scope of the limitation is. Specifically, it is unclear what the boundaries of the scale are. For example, if "uncertain" is at one end of the scale, what is at the other end? Unknown? Undecipherable? Or is it in the opposite direction: Known? The examiner has interpreted the claims to read that "uncertain" is somewhere in the middle of the scale having the boundaries of Unknown and Known. Under this interpretation, "at least uncertain" means the specificity of the second stationary phase could be either unknown or known.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims **2-5 and 27** are rejected under 35 U.S.C. 102(a) as being anticipated by Bailey, Jerome et al (Removing High-Abundance Proteins from Serum, Genetic

Engineering News, 1 November 2003, pp.32, 36-37, Vol. 23, No. 19). Bailey et al. teach a method of evaluating the specificity of a first stationary phase for at least one constituent present in a sample comprising sequentially contacting a sample with at least a first stationary phase (the affinity column) and a second stationary phase (material based on Cibacron Blue) under chromatographic conditions, wherein the specificity of the first stationary phase for at least one constituent present in the sample is uncertain (proteins in Table 1) and the specificity of the second stationary phase for the at least one constituent present in the sample (albumin) is certain (pgs. 36-37 Specific Removal of Targeted Proteins). The sample is contacted with the first stationary phase then the second stationary phase (pgs. 36-37 Specific Removal of Targeted Proteins). The method further comprises contacting the sample with a first stationary phase to bind a fraction of the sample that comprises the at least one constituent; separating the binding fraction from the first stationary phase; and contacting the binding fraction with the second stationary phase (p.37, 2nd full paragraph). The first stationary phase comprises a pharmaceutical agent (polyclonal antibodies) and the method is a method of determining the specificity of the pharmaceutical agent for said at least one constituent present in the sample (pgs. 36-37).

9. Claims **2-5 and 27** are rejected under 35 U.S.C. 102(b) as being anticipated by Jindal et al. (US Pub 2002/0150926). Jindal et al. teach a method of evaluating the specificity of a first stationary phase for at least one constituent present in a sample

comprising sequentially contacting a sample with at least a first stationary phase and a second stationary phase under chromatographic conditions ([0095] and [0122])), wherein the specificity of the first stationary phase for at least one constituent present in the sample is uncertain ([0096] and [0122]) and the specificity of the second stationary phase for the at least one constituent present in the sample is certain ([0115] and [0122]). The sample may be contacted with the first stationary phase then the second stationary phase ([0095] and [0122])). The method further comprises contacting the sample with a first stationary phase to bind a fraction of the sample that comprises the at least one constituent; separating the binding fraction from the first stationary phase; and contacting the binding fraction the second stationary phase ([0122]). The first stationary phase may comprise a pharmaceutical agent and the method is a method of determining the specificity of the pharmaceutical agent for said at least one constituent present in the sample ([139]-[142]).

Response to Arguments

10. Applicant's arguments see Amendment filed September 27, 2007, with respect to rejections under 35 USC 112, 2nd paragraph and with respect to the Mizushima reference have been fully considered and are persuasive. The rejections have been withdrawn.

11. Applicant's arguments filed September 27, 2007 with respect to the rejections under Bailey and Jindal have been fully considered but they are not persuasive.

12. Applicants argue that all of the monoclonal antibodies in the column described by Bailey are of known specificity to serum proteins. On the contrary, the antibodies in the column are the results of the testing reported in this article (paragraph bridging pages 36 and 37) as demonstrated in the language "Table 1 (p.32) shows the proteins identified from the retained fraction by the affinity column." Thus, the antibodies had unknown specificity to the serum proteins prior to the experiments disclosed in the article.

13. The Examiner also disagrees with applicants' argument that Bailey is silent regarding sequentially contacting a sample with a first stationary phase then a second. On page 37, paragraphs 3-5, Bailey discloses such sequential contact.

14. Regarding the Jindal reference, the Examiner disagrees with applicants' argument that Jindal fails to teach a stationary phase with specificity for at least one constituent present in the sample which is certain. Paragraph 115 teaches using a stationary phase (ligand) with known specificity for a constituent (target).

15. Jindal also teaches sequential contact of the sample to the first and secondary phases (paragraph 122).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/Keri A. Moss/
Examiner, Art Unit 1797
5/5/08